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20995 7590 10/18/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER CUMBERLEDGE, JERRY L	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/688,135
Filing Date: October 17, 2003
Appellant(s): TEITELBAUM, GEORGE P.

MAILED
OCT 18 2007
GROUP 3700

Rabinder N. Narula
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 07/09/2007 appealing from the Office action mailed 02/07/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2005/0027257 A1

DAVEY

2-2005

3,155,091

NISSENBAUM

11-1964

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 36-41, 43, 44, 46-51 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Davey (US Pub. 2005/0027257 A1).

Davey discloses a directing sheath (Fig. 13, ref. 10) comprising: a proximal portion (Fig. 13 below) with a proximal end (Fig. 13 below); a distal portion (Fig. 13 below) with a distal end (Fig. 13 below); a central portion (Fig. 13 below) between the proximal portion and the distal portion comprising at least two openings (Fig. 13 below) that extend generally traverse to a longitudinal axis of the directing sheath; and a lumen (paragraph 0042, first sentence, i.e. the passageway) extending through the directing sheath from the proximal end to distal end generally along the longitudinal axis of the directing sheath (paragraph 0042, first sentence) and intersecting the at least two openings (since the openings and lumen converge at the top of the device, near ref. 14, as best seen in Fig. 10); where the directing sheath is scored along its longitudinal axis (Fig. 13, ref. 44) (paragraph 0045, lines 1-8) to allow the directing sheath to be split into

two separate halves and dividing the lumen by peeling the directing sheath apart at either its proximal end or its distal end or both along the scoring (paragraph 0058, lines 5-11). The lumen is configured to receive a guidewire. The directing sheath is scored completely through a sheath wall of the directing sheath, once the device has been completely separated along ref. 44. The directing sheath is scored completely through a sheath wall of the directing sheath along two opposing lines, once the device has been completely separated along ref 44. The directing sheath is scored partially through a sheath wall of the directing sheath (column 0045, lines 1-8). The directing sheath is scored partially through a sheath wall of the directing sheath along two opposing lines (paragraph 0045, lines 1-8). The directing sheath comprises a biocompatible polymer (paragraph 0052). The at least two openings (Fig. 13 below) are sized substantially the same as a portal on a bone screw.

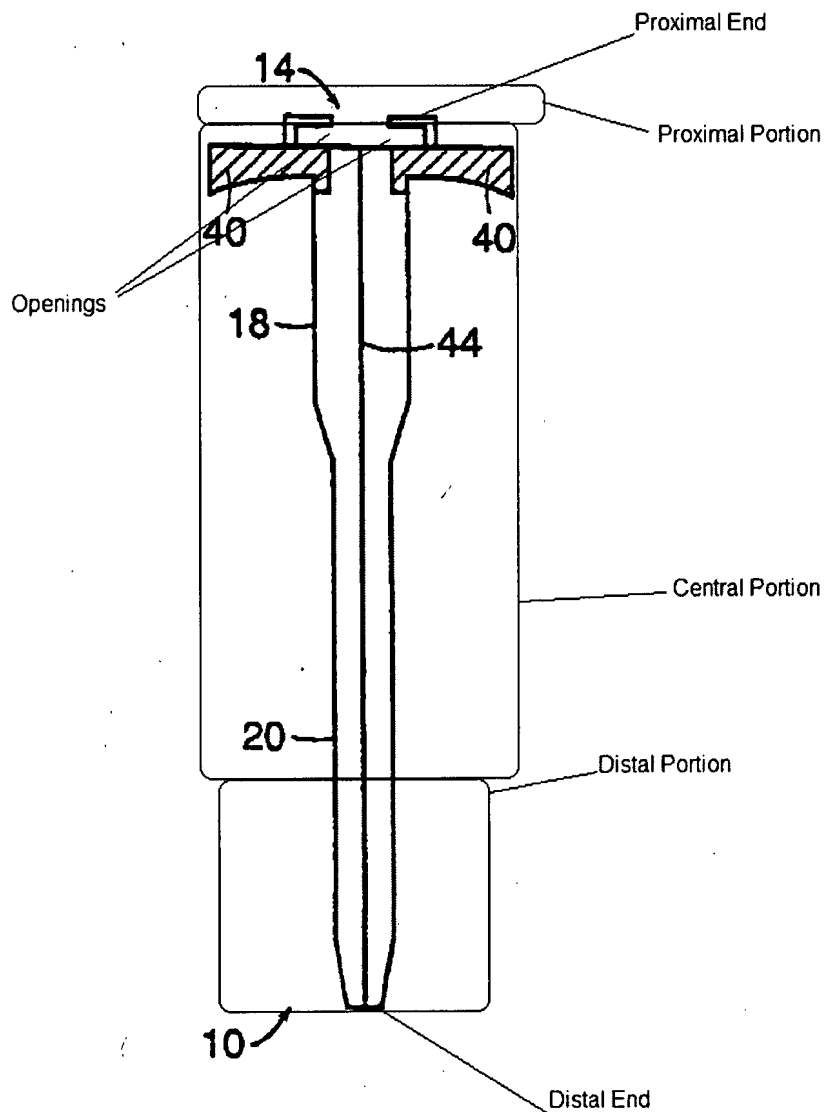
Davey discloses a directing sheath comprising: a body (Fig. 13, ref. 10) extending along a longitudinal axis (the axis extending from near ref. 14 to near ref. 10), the body having a proximal portion (Fig. 13 below) with a proximal end (Fig. 13 below); a distal portion (Fig. 13 below) with a distal end (Fig. 13 below), and a central portion (Fig. 13 below) between the proximal portion and the distal portion; a longitudinal lumen (paragraph 0042, first sentence, i.e. the passageway) extending through the directing sheath from the proximal end to distal end generally (paragraph 0042, first sentence); at least two openings (Fig. 13 below) that extend through the central portion (Fig. 13 below) of the directing sheath generally transverse to a longitudinal axis of the directing sheath (Fig. 13 below) intersecting the longitudinal lumen (Fig. 13 below); and where

the directing sheath is scored along its longitudinal axis (Fig. 13, ref. 44) (paragraph 0045, lines 1-8) to allow the directing sheath to be split into two separate parts and dividing the longitudinal lumen by peeling the directing sheath apart at either its proximal end or its distal end or both along the scoring (paragraph 0058, lines 5-11). With regard to the phrase "...at least two openings that extend through the central portion ...", it is noted that the examiner is considering the openings to be extending through the central portion, but not entirely through (e.g. partially through). The lumen is configured to receive a guidewire. The directing sheath is scored completely through a sheath wall of the directing sheath, once the directing sheath has been completely separated along ref. 44. The directing sheath is scored completely through a sheath wall of the directing sheath along two opposing lines, once the device has been completely separated along ref. 44. The directing sheath is scored partially through a sheath wall of the directing sheath (paragraph 0045, lines 1-8). The directing sheath is scored partially through a sheath wall of the directing sheath along two opposing lines (paragraph 0045, lines 1-8). The directing sheath comprises a biocompatible polymer (paragraph 0052). The at least two openings (Fig. 13 below) are sized substantially the same as a portal on a bone screw

With regard to statements of intended use and other functional statements (e.g. ...configured to receive a guidewire...), they do not impose any structural limitations on the claims distinguishable over the device of Davey, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not

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require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 42, 45 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davey (US Pub. 2005/0027257 A1) in view of Nissenbaum et al (US Pat. 3,155,091).

Davey discloses the claimed invention except for the directing sheath comprising a radiopaque filament running the longitudinal length of the directing sheath from the proximal end to the distal end and passing around each opening in the central portion.

Nissenbaum et al. disclose a radiopaque filament (Fig. 2, ref 11) (column 2, lines 5-8) running the length of a sheath (Fig. 2, ref. 10) from the proximal end to the distal end (column 2, lines 21-26), the radiopaque filament being used to determine the location of the sheath in the body (column 2, lines 58-63).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the directing sheath of Davey with a radiopaque filament running the length of a sheath from the proximal end to the distal end as taught by Nissenbaum, the radiopaque filament being used to determine the location of the sheath in the body (Nissenbaum et al., column 2, lines 58-63). With regard to the statement "...a radiopaque filament...passing around each opening in the central portion," since the filament of Nissenbaum would run from the proximal end of the directing sheath of Davey to the distal end of the sheath of Davey, and since the openings of Davey are between the proximal and distal ends, the filament would pass near each of the openings of Davey. The definition of "around", according to the

Merriam-Webster Online Dictionary, is "near." Thus, if the references were combined as taught, the radiopaque filament of Nissenbaum would run the length of the directing sheath of Davey and the filament would pass around each of the openings of Davey.

(10) Response to Argument

Regarding the rejection of claims 11, 36-41, 43, 44, 46-51 and 53 under 35 U.S.C 102(e) as being anticipated by Davey (U.S. Publication No. 2005/0027257 A1), herein Davey:

Appellant states on page 9, "Davey discloses an introducer sheath 10 that includes " a body portion 12 and a proximal hub portion 14, with a passageway extending through the entire length of the sheath 10." Davey, specification [0042] and [0045]; Fig. 13. As illustrated in Fig. 13 reproduced below, the sheath 10 only has an opening at the distal end of the sheath 10 and an opening at the proximal and of the sheath 10 that provide access to the passageway extending through the sheath 10. The central portion of the sheath 10 has no openings whatsoever."

Appellant further states on page 10 "As is clearly evident from the marked up version of Fig. 13, the Examiner has misinterpreted Fig. 13 in several respects. For example, the Examiner circled the topmost portion of the hub 14 and cited it as the proximal portion of the sheath 10. The central portion of the sheath 10, as marked by the Examiner, is shown encompassing both the hub 13 and a portion of the sheath 10. The "openings" referred to in the marked up version of Fig. 13 actually point to a single

irregularly shaped opening in the hub that is commonly found in the hub portion of peelable introducers.”

The examiner respectfully disagrees with Appellant that the portion labeled as the “proximal portion” in the marked up drawing cannot be considered to be a proximal portion of the sheath. The Examiner asserts that it is reasonable for one of ordinary skill to consider the entirety of Fig. 13 to be a sheath. Thus, the portion labeled the “proximal portion” by the Examiner can be considered to be a proximal portion of a sheath.

The examiner also respectfully disagrees with Appellant that there is a single opening disclosed and not “openings”. The device is scored along ref. 44 in order to allow the device to be split (paragraph 0058, lines 5-11). Furthermore, ref. 40, which is referred to by Davey as a “hub”, can also be split (paragraph 0012). When the device is split in two halves, there will be a right half with an opening and a left half with an opening, the openings being the portions pointed to by the Examiner in marked up Fig. 13.

The rejection of claims 11, 36-41, 43, 44, 46-51 and 53 under 35 U.S.C 102(e) as being anticipated by Davey (U.S. Publication No. 2005/0027257 A1) is deemed proper.

Regarding the rejections of claims 12, 42, 45 and 52 under 35 U.S.C. 103(a) as being unpatentable over Davey (U.S. Publication No. 2005/0027257 A1) in view of Nissenbaum et al. (US Patent No. 3,155,091).

Applicant has not provided any further argument as to why the rejections under 35 U.S.C. 103(a) are improper other than the arguments already addressed above. For

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the reasons set forth above, the rejections of claims 12, 42, 45 and 52 under 35 U.S.C. 103(a) as being unpatentable over Davey (U.S. Publication No. 2005/0027257 A1) in view of Nissenbaum et al. (US Patent No. 3,155,091) are deemed proper.

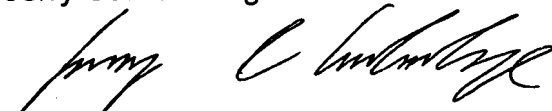
(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

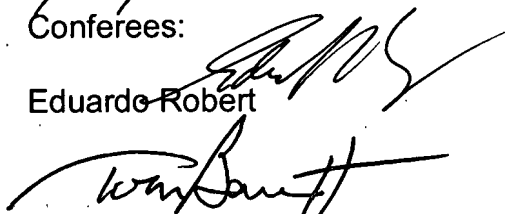
Respectfully submitted,

Jerry Cumberledge



Conferees:

Eduardo Robert



Tom Barrett

